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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,567	03/26/2001	Kumar Subramanian	Kum13Sil.Lan	9915

7590 04/07/2003

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NEW YORK, NY 10036-2711

EXAMINER

DAVIS, DANIEL J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 04/07/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/817,567

Applicant(s)

SUBRAMANIAN ET AL.

Examiner

D Jacob Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

Some of the references have been submitted, but a 1449 form listing all references is not included.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24, 25, 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Gartstein et al. (US 6,379,324). Illustrated in Fig. 21 (Figs. 18-21 illustrate the needle formation process), Gartstein disclose a microlancet device comprising an elongated single crystal silicon substrate 410 (Col. 14, lines 53-et seq.) having a base end 410 A,B, and a penetration end, which is the pointed portion of the lancet. They describe using chamber 470 to dispense medicine. However, it may also be used to receive a blood sample. Illustrated are cylindrically shaped needles, but tapered needles are also anticipated (Col. 17, lines 1-6). Tapered needles inherently have a chiseled shape. The device is inherently disposable.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 27, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gartstein. Gartstein are silent regarding the outer diameter dimension. However, they do state, "any microneedle length or diameter that is appropriate for a particular chemical fluidic compound and for a particular skin structure could be used, without departing from the principles of the present invention." (Col. 17, lines 7-25). Moreover, the courts have concluded that a change in dimension, degree, size, shape, etc. without special functional significance is not patentable. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the outer diameter of the needle extends from about 50 micrometers to about 250 micrometers to accommodate a particular chemical fluidic compound or skin structure.

Gartstein describe a preferred needle length different from that claimed by applicants. Nevertheless, it would been obvious to one of ordinary skill in the art at the time the invention was made to make the length of the needle about 1 mm to about 3 mm to accommodate a particular chemical fluidic compound or skin structure.

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Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gartstein in view of Lin et al. (US 5,591,139). Gartstein disclose a silicon nitride layer 426 that is removed in an intermediary step (Fig. 20). They also disclose an oxide layer 416,418 to seal the final product. Lin also disclose a microneedle having a silicon substrate. However, instead of using a silicon oxide sealing layer, they use silicon nitride to seal the substrate (Col. 6, lines 41-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a silicon nitride layer to seal the silicon substrate.

The oxide layer described by Gartstein is about 5000 Angstroms thick, which is about the claimed 2000 Angstroms. The silicon nitride layer would take on a similar protective thickness as the oxide layer.

### ***Response to Arguments***

Applicants' arguments with respect to claim 24 have been considered but are moot in view of the new ground of rejection.

### ***Conclusion***

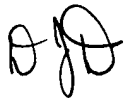
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone

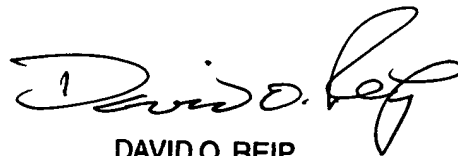
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numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



DJD  
April 1, 2003



DAVID O. REIP  
PRIMARY EXAMINER